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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,696	03/27/1998	PATRICIA A. BILLING-MEDEL	6067.US.O1	5914

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EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

21

DATE MAILED: 04/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/049,696

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9,10,12-14,16 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) 7,9,10,12-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1631.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims 7, 9, 10, 12-14, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 8.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, misdescriptive, and inaccurate.

- (a) The recitation of "equivalent degenerate coding sequences thereof" (claims 19, 23, 25, and 26) is vague and indefinite because the reading frame is not specified.
- (b) The recitation of "recombinant techniques" (claims 20, 28, and 31) is vague and indefinite because there is no art recognized set of techniques that is regarded as "recombinant techniques." The instant application does not distinguish between recombinant techniques and non-recombinant techniques. Additionally, the method of making the polynucleotides does not further limit or describe the polynucleotides.
- (c) The recitation of "synthetic techniques" (claims 21, 29, and 32) is vague and indefinite because there is no art recognized set of techniques that is regarded as "synthetic techniques." The instant application does not distinguish between

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synthetic techniques and non-synthetic techniques. Additionally, the method of making the polynucleotides does not further limit or describe the polynucleotides.

- (d) The recitation of "an amino acid sequence" (claim 27) is vague and indefinite because it is not clear whether the claim is limited to polynucleotides that encode the entire amino acid sequence of SEQ ID NO: 41 or only a portion of it.
- (e) The recitation of "amino acid sequence of SEQ ID NO: 20" (claim 30) is misdescriptive and inaccurate because SEQ ID NO: 20 is a nucleotide sequence, not an amino acid sequence.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yu et al (WO 96/39419 (December 12, 1996)). Yu et al discloses nucleotide sequences that contain SEQ ID NOs: 13 and 15 and contain a sequence that is encoded by SEQ ID NO: 15 (see the alignments that are attached to the reference). Additionally, Yu et al discloses expression vectors and host cells for the expression of the polynucleotides disclosed in the reference (e.g., see abstract and pages 22-28). Thus, the polynucleotides of Yu et al and the expression vectors and host cells are embraced by the claims.

Claims 19-32 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yu et al (U.S. Patent No. 5,733,748). Yu et al discloses sequences encoded by SEQ ID NOs: 12 and 16 and a sequence 100% identical to SEQ ID NO: 41. The reference further discloses expression vectors and host cells of the expression of the polynucleotides disclosed in the reference (e.g., see the abstract, columns 12-15 and columns 23-24). Thus, the polynucleotides of Yu et al and the expression vectors and host cells are embraced by the claims.

Claims 19-22 and 25-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Adams et al (Nature 377 (Supp) 3 (1995)). The extensive tables in Adams et al have not been provided with this Office action. Should applicants wish a copy, it will be provided upon request. Adams et al discloses a polynucleotide that contains SEQ ID NO: 15 (see the alignment attached to the copy of the reference). Since the polynucleotide of Adams et al was sequenced, it was necessarily isolated and at some time contained within a vector in a host cell. Thus, the polynucleotides, vectors, and host cells of Adams et al are embraced by the claims.

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Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al (Nature 377 (Supp) 3 (1995)) in view of applicants' admitted state of the prior art (instant application at pages 35-40). The discussion of Adams et al hereinabove is incorporated here. Applicants acknowledge expression vectors, host cells, and methods of heterologous gene expression to be old (instant application at pages 35-40). It would have been obvious for one of ordinary skill in the art at the time the invention was made to express the polynucleotides of Adams et al in the admittedly old manner in order to produce large amounts of sequence specific polypeptides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



JAMES MARTINELL, Ph.D.
SENIOR LEVEL EXAMINER